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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,711	04/05/1999	TAKESHI SAKAI	1/F3511PTUS	1469

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EXAMINER
WANG, SHENGJUN

ART UNIT	PAPER NUMBER
1617	30

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/269,711	SAKAI ET AL.	
	Examin r	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted December 26, 2002 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibino et al. (JP 01160988) in view of Gilchrest et al. (US patent 5,353,440), Giaccia et al. (US Patent 5,646,185) and Nakai et al. (U.S. patent 5,672,603, of record), and in further view of Nelson ("Isolation and Purification of lipids from Biological Matrices," in Analysis of Fats, Oil and lipoproteins, Edited by Edward G. Perkins, 1993, of record).

Hibino et al teaches that a glycerolipid is useful for treating cancer. See the abstract.

Hibino et al. does not teach expressly to employ glycerolipid from tea, cereal or mushroom for introducing apoptosis.

However, Gilchrest et al. teaches that natural glycerol lipids (diacylglycerols) are known to be similarly active as physiological activator of PKC. See, column 3, lines 52 bridging column 4, lines 59. Giaccia et al. suggests that PKC activators, including diacylglycerols, are useful in treating cancers. See, particularly, column 6, lines 6-27, and column 12, lines 18-46.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ natural glycerolipids, including those isolated from tea and mushroom, for treating cancers.

3. A person of ordinary skill in the art would have been motivated to employ natural glycerolipids, including those isolated from tea and mushroom, for treating cancers because all the natural glycerolipid are expected to be similarly useful in treating cancer. Regarding the functional limitation, "inducing apoptosis," note it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. Further, Nakai et al. teaches that apoptosis is a physiological process which may occur under various physiological condition. See, column 1, lines 44-67. e.g., Apoptosis is involved in cancer treatment when the cancer cells are killed. See column 2, lines 15-39. It is concluded that apoptosis regulating compounds or composition are useful as anticancer agent, antiretroviral agent, and therapeutical agent for autoimmune disease, for thrombocytopenia, for Alzheimer's disease and for various types of hepatitis, tumor metastasis inhibiting agent. See, column 4, lines 45-51. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and

purification. See page 45. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45. Therefore, the claimed "method of inducing apoptosis would reading on treating cancers.

Regarding the particular method of isolation and purification of glycerolipid, Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45. The employment of acid/base treatment in the process of making the glyceroglycolipid is seen to be obvious since the separation/purification of prior art glycerolipids would be expected to increase the concentration of the active glycerolipids in the instant composition and is considered within the skill of artisan because acid treatment is a well known technique for purification and separation.

Response to the Arguments

Applicants' amendments and remarks submitted December 26, 2002 have been fully considered. They are persuasive in overcome the rejection under 35 U.S.C. 102, but are not persuasive with respect to the rejection set forth above.

Applicants argue that the cited references do not teach expressly "that apoptosis can be induced by isolated glycerolipid" the examiner notes if a compound from natural source was known to be useful for a therapeutic utility, the employment of "isolated" or purified form of the compound for the same utility would have been prima facie obvious.

The examiner agrees that "***new use*** of a ***known process***, machine, manufacture, composition of matter of material" is patentable over the ***known process***, machine, manufacture, composition of matter of material. However, what claimed herein is nothing new but what

exactly the cited references have suggested, i.e., administering glycerolipid to cancer patients. (note the claimed invention has no limitation as to whom the glycerolipid is administered)

Applicants argue that Giaccia et al. and Gilchrestet al. teach away from the instant invention because both references suggest a different mechanism for treating cancer. The arguments are not probative. Particularly, the teaching provides motivation to employ glycerolipid, including those from natural source for treating cancer. Further, one particular mechanism does not exclude other mechanism. Teaching that glycerolipid actives PKC does not teaches the compounds does not introduce apoptosis. Further, Apoptosis is a process of cell death, it obviously involves many enzymatic activities, no teaching on the record shows that PKC activation is not part of apoptosis. (see Nakai et al.)

The examiner does not consider, or be assumed, that anticancer agents are useful at inducing apoptosis. The examiner considers the instant claim read on treating cancer patient with glycerolipid. As discussed above, it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

RUSSELL TRAVERS
PRIMARY EXAMINER

Examiner
Shengjun Wang
March 21, 2003